Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

'01 JAN 26

RE: Docket No. 00D-1598

Dear FDA,

I am writing about your "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." After reading your background discussion of the draft I am left wondering who our FDA represents, the people – or- the biotech corporations. I find it curious that you place the burden of proof as to biotech food safety on the individuals and groups who may write in protest of your draft rules. In your discussion you write, "*Most of the comments that addressed labeling requested mandatory disclosure of the fact that the food or its ingredients was bioengineered or was produced from bioengineered food. However, these comments did not provide data or other information regarding consequences to consumers from eating the foods or any other basis for us to find under section 201(n) of the act that such a disclosure was a material fact. Many of the comments expressed concern about possible long-term consequences from consuming bioengineered foods, but they did not contend that any of the bioengineered foods already on the market have adverse health effects. The comments were mainly expressions of concern about the unknown.*" How could the long term consequences of bioengineered food be known when they haven't been around long enough to perform long term studies? Do you expect that the general public will be knowledgeable enough on the technical aspects of this issue to provide you scientific proof of the dangers? Do you think that those of us purchasing and eating these foods have time and expertise to test them on laboratory animals before we eat them? Fortunately, there are individuals and organizations, which of their own accord and at their own expense (with little or no financial gain to their work, unlike the biotech corporations) have explored the issue and uncovered numerous questionable conditions. I am aware they have raised these issues with your department, therefore will not elaborate upon them.

Should not the burden of proof lie with those corporations desirous of selling their biotech products rather than the general public who has nothing to gain except their own safety? Have you so soon forgotten the pesticide debacle of the 60's? The corporations creating those pesticides convinced the government and public that there was no danger. The situation was the same then as it is now with bioengineered foods. In both cases we did not know what the future would hold if the products in question were used wide scale. Today we regret the use of DDT and dioxin, just to name a couple of the worst. Had those chemicals been adequately tested, they would never have made it to the market place – that is, if our government's protection agencies had done their job in enforcing thorough testing.

It is so clear to me that the job of proving safety in this matter lies with the corporations promoting these products. I cannot understand how an agency that purports to protect the public cannot see this. It is interesting to note in your draft that you state, "*For example, we are seeking comment on whether, and how, statements like "GM free" or "no genetically engineered material" can be made without being false or misleading. In the guidance document, FDA advises that the term "free" may be difficult to use without being false or misleading. If it implies "zero," it may be very difficult to substantiate.*" I must ask myself, what exactly is 'false or misleading' in this issue. Is it not 'false or misleading' for corporations to sell their genetically modified products to the general public without informing them? To me, this is the epitome of 'false and

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misleading' actions, however FDA seems to have no conscience pangs whatsoever about this activity on the part of corporations. Why is that so? With behavior like that, do you not wonder why at least a portion of the public perceives FDA as 'in the pocket' of the biotech corporations? FDA provided rules in the past requiring manufacturers to list all ingredients in their processed food products. Why did FDA require such actions? Was it not to protect and inform the public? How does labeling of genetically modified food products differ from listing food ingredients? Is not the spliced frog gene in a broccoli plant not an unexpected 'ingredient' just as mono-sodium glutamate is in a can of soup? I have a hard time understanding how your stand on this issue could hold up in court, based on your past stance regarding food labeling. I have an even harder time understanding how you, in good conscience, can believe you are protecting the public in this matter. I always thought that protection of the public was the primary mission of FDA. Maybe I am mistaken.

Looked at from a higher perspective, the issue of labeling genetically altered food is ultimately an ethical and philosophical one. It seems that the creators of biotech foods are so enamored with their intellectual creativity that they believe they can discard (or ignore) the wisdom needed to utilize their creativity in a manner of benefit to the public. It seems they truly believe they are acting in the public's best interest because they shall supply the world with an abundance of food. Our scientists and corporations thought the same thing about pesticides (many still do). Anyone who studies, however, the root cause of deficient diets in this world knows that the real causes are issues such as poverty, unequal food distribution, and lack of education. Food scarcity as a cause of world hunger is a myth (see 'Escaping Hunger, Escaping Excess' World Watch Magazine, July/August 2000). For example, there is enough food thrown away in American restaurants and supermarkets to feed a large percentage of the under nourished people of the world. It is fine if the creators of biotech foods want to play god, but do they have God's wisdom? I suspect not. Maybe the FDA believes they have that level of wisdom. Maybe that is why biotech foods receive very little testing before reaching the marketplace. Or maybe FDA already let the cat out of the bag and now cannot possibly keep up with the onslaught of bioengineered food waiting to enter the market place.

I am surprised at myself for even bothering to write this letter. As with many Americans, I am so accustomed to our government ignoring the needs of the public that normally, I just shrug my shoulders at issues such as this and do nothing. All too often it seems we the public are powerless against the financial might of the multi-national corporations. It appears that our only strength is in our voice, and I am choosing to express mine now. The public voice served to overturn USDA's original proposed organic food rules. Maybe public voice can also breathe some sense into this issue of labeling bioengineered food.

I have studied the activities of this world long enough to know that the primary goal of Western society is to achieve material wealth. The cost of that achievement to humanity or to the Earth does not seem to matter. It is clear that economically, the corporations have much to lose in this matter, otherwise they would not be so fearful of biotech labeling. You don't hear them complaining about labeling if adding more words to their label helps them sell their product. Clearly, their intent is more towards profit than toward public well being. I am embarrassed as an American to hear us criticize the Europeans for not accepting our biotech foods while doing everything in our power to force such foods on them under the auspices of 'fair trade'. I live in America and I have traveled to France and Greece. The standard American fast food diet is a travesty in comparison to the healthy diets I observe in Europe. Who are we to think we can force our nutritionally poor diet (and subsequent health problems) on the Europeans? The current stance of FDA in the matter of labeling is directly related to this matter of international relations. International tensions would be eased if FDA had the courage to take the high road and

require the elimination of "false and misleading" information on the part of the bio tech companies by requiring them to label their bioengineered foods.

From where I sit as "Joe Citizen" it is very hard to determine why FDA sides with corporations on this matter. Is not the primary role of FDA to protect the public in food safety matters? It is hard not to become suspicious of our government when witnessing such activities as FDA's current stance on labeling genetically engineered food.

In closing, I ask that you not get lost in the forest of technical and legal matters related to biotech foods, but instead look at this issue from a higher elevation. Use your conscience and your heart rather than only your head to determine what FDA decision in this matter would most truly represent the best interests of America (and the world) today and in the future.

Thank you for your time in this matter.

Sincerely,

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